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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/019,446	12/31/2001	Heiner Stegmann	01234	4344

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DENNISON, SCHULTZ, DOUGHERTY & MACDONALD
1727 KING STREET
SUITE 105
ALEXANDRIA, VA 22314

EXAMINER

ASTORINO, MICHAEL C

ART UNIT	PAPER NUMBER
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3736

DATE MAILED: 08/16/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/019,446

Applicant(s)

STEGMANN, HEINER

Examiner

Michael C. Astorino

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 May 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 20-25 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 20-25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

The examiner acknowledges the response filed May 9th, 2004, wherein claims 12-19 have been canceled and claims 20-25 are pending.

The examiner under 37 C.F.R. § 1.105 entitled, "Requirements for Information," requires a submission from the applicant information regarding anaerobic threshold testing, Bruce Protocol and lactate testing in which applicant is aware along with nutritional guidelines commonly associated therewith. In addition, the applicant should also provide information relating to distinguish Bruce Protocol test where an athlete runs on a treadmill to exhaustion from anaerobic threshold testing, and provide information on any other physical performance testing where anaerobic threshold testing and/or lactate testing is either directly or indirectly measured, calculated and/or can be derived from the measurements and/or calculations. The submission of the information is reasonably necessary in order to properly examine or treat the claimed invention.

Claim Objections

Claim 24 is objected to because of the following informalities: line 7 of the claim, "is plotted" should be removed from the claim limitation since it is redundant with respect to the beginning of the claim limitation, "plotting a measurement curve...". Appropriate correction is required.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 20-25 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter since the claimed invention fails to produce a useful, tangible, and concrete result.

Claims 20-25 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter that fails to produce a useful, tangible, and concrete result. The claimed invention does not produce a “tangible” result in the sense that it merely manipulates abstract ideas without producing a physical transformation or conversion of the subject matter expressed in the claim to produce a change of character or condition in some physical object. See In re Warmerdam, 31 USPQ2d 1754 (Fed. Cir. 1994); In re Schrader, 30 USPQ2d 1445 (Fed. Cir. 1994). The steps of the claimed method are effectively no more than ideas and concepts that are deemed abstract in nature.

In this case, the method comprises, according to claim 12, two steps. The first step is a determining performance capacity. The second step is determining a stress state of the person. The last step is regulating carbohydrate, fat, and protein percentage requirements based on the determined performance capacity. The “determination” and “regulating” steps are not a tangible entities having substance. As such, claim 20 recites the manipulation of abstract ideas, lacks practical utility, and fails to achieve a useful, concrete, and tangible result. The regulation of a diet does not produce concrete, substantially repeatable results.

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Claims 20-25 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

**Claims 20, 21, and 25 are rejected under 35 U.S.C. 102(b) as being anticipated by
Chance US Patent Number 5,081,991 A.**

In regards to claim 20, Chance teaches a method for adjusting nutrition in a person subjected to physical stress, comprising the steps of:

determining performance capacity of the person by measuring individual anaerobic threshold of the person (column 10, lines 30-47) ;

determining a stress state of the person in relation to the measured individual anaerobic threshold (column 2, lines 12-51); and

regulating at least one of fat, protein and carbohydrate consumption of the person as a function of the determined stress state (column 11, lines 43-45).

During the normal use and operation of the Chance teaching, the method steps set forth by applicant are inherently performed.

In regards to claim 21, Chance teaches a method according to claim 20, wherein performance capacity is determined by measuring lactate accumulation rate delta A at and above the individual anaerobic threshold (column 10, lines 30-47) .

In regards to claim 25, Chance teaches a method according to claim 20, wherein the performance capacity determined under a stress selected from the group consisting of a running test, a swimming test, a stepping test and ergometry with graduated or continuous stress increase with and without breaks (see figure 1, and column 2, lines 15-20).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

**Claims 22 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over
Chance US Patent Number 5,081,991 A.**

In regards to claim 22, Chance discloses “wherein the stress occurs in a person over an extended period of time below the determined individual anaerobic threshold,” (column 10, lines

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3-47) and monitoring different nutritional programs but does not specifically disclose “the fat and the carbohydrate percentage of the nutrition are adjusted comparatively higher than the protein percentage.” However, the examiner takes official notice that a fat and carbohydrate percentage of nutrition adjusted comparatively higher than the protein percentage, would be obvious to one in the art at the time of the invention to test for fat and carbohydrate percentages comparatively higher protein.

In regards to claim 24, regarding finding the lactate accumulation rate delta A, Chance discloses a means by which to find lactate concentration (column 10, lines 30-47), but does not specifically disclose the method of claim 24. However, at the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to use the method of claim 24 to determine lactate accumulation rate delta A because Applicant has not disclosed that method of determining lactate accumulation rate delta A provides an advantage over any other method of determining lactate accumulation rate delta A, that is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant’s invention to perform equally well with Chance’s method of determining lactate accumulation rate delta A since both will accurately determine lactate accumulation rate delta A.

Claim 23 is rejected under 35 U.S.C. 103(a) as being unpatentable over Chance US Patent Number 5,081,991 A as applied to claim 21 above; and further in view of Kornstad

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et al., “Low Calorie diet, exercise and hypertension. 2 pilot studies using a protein-rich low-calorie diet powder”

Chance discloses in column 10, lines 3-14, “From the profile of FIG. 5, it is possible to obtain a good indication of the genetic capability of the subject, its adaptation to training, and its nutritional status. The above-described test can be repeated at appropriate intervals during a training program, and by comparing the efficiency profiles obtained at different times, the effects of training and nutrition can be readily quantified. Thus, this NMR testing equipment can be used to determine which training and nutritional regimes permit optimal expression of a subject's genetic potential for competitive performance or any other type of situation that can be simulated on the treadmill.” In addition, in column 11, lines 52-57 Chance states, “Another way in which the apparatus of FIGS. 1-4 may be used is to evaluate the ability of a subject to recover from exercise. Such ability is an indication of the intrinsic genetic capability of the animal, the impact of training and nutritional regimen upon recovery time, or, indeed, the effect of overtraining.” However, Chance does not specifically disclose what changes in nutritional regimes are tested, specifically in regards to fats, carbohydrates and proteins percentages in the subject's diet.

Kornstad et al., teaches using a protein rich low-calorie diet powder on an exercise treadmill physical performance test. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the Chance nutritional test in view of high protein diet test of **Kornstad et al.**, since **Kornstad et al.**, states the diet helped the subject achieve better blood pressure control which furthers Chance nutritional objective since it aides the subject to obtain maximum performance.

Response to Arguments

The applicant's preemptive arguments to overcome a rejection under 35 U.S.C. 101 by adding new claims are not persuasive. The applicant contends that the method is a physical method having physical steps. However, the claims as cited do not require the performance of physical steps. The first determination step does not require a physical measurement. In fact, a well-known means of measurement of anaerobic threshold occurs when the person mentally calculates anaerobic threshold as 80-90% of a person maximum heart rate or just the point at which a person can't talk without gasping for breath. The applicant does not state affirmatively that the second determination step requires a physical step nor is it the examiner's belief that the step has a physical step. Lastly, a regulation step can be performed by doing nothing, assuming the person is already performing the prescribed nutrition regimen. Therefore, no physical step is even required to perform the method.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period

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will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Michael C Astorino** whose telephone number is **571-272-4723**. The examiner can normally be reached on Monday-Friday, 8:30AM to 3:30PM.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on 571-272-4726. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Michael Astorino
August 8, 2005



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